



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

April 25, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-43

Joyce Cassidy
President
Cassidy, Inc.
495 Kenny Road
St. Paul, Minnesota 55101

Dear Ms. Cassidy:

Inspection of your plant by FDA Investigator Mary Chestolowski revealed products adulterated under Section 601(e) of the Federal Food, Drug and Cosmetic Act (the Act) and/or in violation of Section 1454(c)(3)(B) of the Fair Packaging and Labeling Act (FPLA). These include:

1. The use of FD&C Blue No. 2 as a colorant in the manufacture of A-VITAGEN Red Ginger Shampoo and Blue Mulva Shampoo. Since there is no color additive regulation allowing for the use of this color in cosmetics, the products identified above are adulterated under Section 601(e) and in serious violation of the Act.
2. The ingredient declaration appearing on the labels for the Flax Seed Gel, Sculpturing Gel, Witch Hazel Hair Spray, Professional Hair Spray, G.T. Pearl Shampoo, Blue Mulva Shampoo, Body Wash, Red Ginger Shampoo, Hair Moisturizer, and Chamomile Shampoo differ from the production batch records. Thus these products are in violation of Section 1454(c)(3)(B) of the Fair Packaging and Labeling Act (FPLA) in that the product labels fail to bear an accurate declaration of the name of each ingredient as required by Title 21 Code of Federal Regulations (CFR) 701.3. Examples include:

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- A. The ingredient declarations refer to "aqueous extract of..." or "alcoholic extract of..." rather than listing the "water" or the "alcohol" ingredient in its proper descending order of predominance in the formulation.
- B. The color additives used in the product formulations are not listed in the ingredient declarations.
- C. The ingredient declarations include parenthetical statements of alternate ingredient names (e.g., "Vitamin E") and/or function (e.g., emollient/moisturizer).
- D. The ingredient declarations include nomenclature other than that specified in §701.3(c), (e.g., "Vitamin E Oil," "Extract of Cherry Bark, Almond Bark, Rosemary and Nettles," "Natural Essential Oils") and the parenthetical term "(and)" between various ingredients.
- E. The ingredient declarations fail to declare other ingredients listed in the production batch record, while the label declares ingredients which are not listed as ingredients in the product formula.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of cosmetics, you are responsible for assuring that your overall operation and the products you manufacture and distribute, as well as your labeling, are in compliance with the law.

You should take prompt action to correct these deviations. Failure to promptly correct them may result in enforcement action without further notice, such as seizure and/or injunction.

Mr. Durre stated he was on schedule with most of the items discussed with Investigator Chestolowski and would be making changes in the way the ingredients are listed. You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working

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days, state the reason for the delay and the time within which the corrections will be completed.

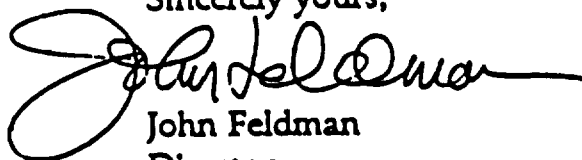
The A-VTTAgen Flax Seed Gel, Sculpturing Gel, and A-VTTAgen Witch Hazel Hair Spray includes the term "sunscreen" on the label. FDA has proposed to amend the regulations for cosmetic to require use of the term on cosmetics be qualified by describing the cosmetic benefit provided by the sunsreen. For example: "This product contains a sunsreen that assists in protecting the hair from damage by the sun." The Agency feels the term "sunsreen," used by itself on a cosmetic, may be misleading because it implies a therapeutic effect to consumers. Pages 28205-28206 of the May 12, 1993, Federal Register are enclosed for your information. Note that at this time the rule is only proposed.

For your information, the parenthetical listing of ingredients as "color enhancement" and "color" may cause the product to be adulterated under Section 601(e) of the Act if these ingredients meet the Section 201(t) and 21 CFR §70.3(f) and (g) color additive criteria. We would also add that terms such as "regenerates cells" and/or "regenerates hair" may cause your products to be considered drugs and thus subject to drug requirements, i.e., registration, listing, GMPs, etc.

We acknowledge the letter from Rod Durre dated February 14, 1997, to Mary Chestolowski. Mr. Durre inquired if other firms had some sort of exemption from FDA regulations. We can assure you it is not possible for a firm to have an exemption from FDA regulations.

Your reply should be sent to Compliance Officer Judy E. Heisick at the address indicated on the letterhead.

Sincerely yours,



John Feldman
Director
Minneapolis District

JEH/ccl
Enclosure